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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,260	03/16/1998	A.K. GUNNAR ABERG	4821-306	9369

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/039,260	ABERG ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 14, 2004 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,50,52-61 and 63-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,50,52-61 and 63-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-47, 49, 51 and 62** have been cancelled, no claims have been amended, and no new claims have been added as per the Request for Continued Examination (RCE) of March 14, 2005. Receipt of the Statement filed under 37 C.F.R. §3.73(b) is noted. No additional Information Disclosure Statements (IDSs) have been filed as of the date of completion of this Office Action.

Claims **48, 50, 52-61 and 63-68** remain in the case.

Claim **65** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **65** the term "elixir" is indefinite because the instant claim fails to particularly point out what mixture of pharmaceutically acceptable carriers has been added to make "an elixir" of DCL and "a decongestant." Inspection of PTO-892 references **S and T**
i) at page 784 (column 2, "Elixir of Casara Sagrada" following "Aromatic Cascara Fluidextract") (ref. **T**),
ii) at page 1099 (column 1, "Tylenol with Codeine Elixir" following "Narcotic Analgesic Combinations") (ref. **S**), and
iii) at page 1302 (column 2, following "Hydroalcoholic Diluting Agents) (ref. **T**)
reveal that the generic term "elixir" means different things depending upon which active ingredients are included in the final liquid composition. Clarification of the intended meaning of the noted term is respectively requested (the actual mixture of carriers has not been specified).

Applicant's arguments with respect to claim 65 have been considered but are deemed to be moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **48, 50, 52-53, 63 and 65** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Villani et al. '716** (PTO-1449 ref. **AC**).

In the Villani et al. reference at column 8, lines 42-46, the combination of descarbethoxyloratadine (DCL) and a decongestant in a single pharmaceutical composition is generically taught. Applicant is referred to column 24, lines 44-54 wherein administration to a human host is specifically taught.

Applicant's arguments filed August 15, 2003 (Amended Appeal Brief) and February 9, 2004 (Reply Brief) have been fully considered but they are not deemed to be relevant because of the amended grounds of rejection is in effect a new grounds of rejection.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **48, 50, 52-54, 61 and 63-65** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Villani et al. '716** (PTO-1449 ref. **AC**) in view of **Berkow et al.** (PTO-892 ref. **R**).

The instant claims are directed to pharmaceutical compositions wherein the antihistamine DCL and a decongestant are the active ingredients, and wherein the decongestant is specified as pseudoepidrine in two claims. The instant claims are are directed to various specific ranges of dosage and methods of administration including the oral, parenteral, rectal, transdermal and aerosol routes.

Villani et al. '716 discloses at column 8, lines 42-46, the combination of DCL and an decongestant in a single pharmaceutical composition. This reference discloses the oral, parenteral, rectal, and transdermal routes of administration of the noted composition. This

reference does not disclose pharmaceutical compositions wherein the specific decongestant has been specified or wherein the route of administration is by the aerosol route.

Berkow et al. discloses at p. 326 under the heading "Treatment," lines 1-6, in particular lines 4-6, the combination of an antihistamine with the decongestant "pseudoephedrine" in a single pharmaceutical composition. Berkow also teaches the administration of such compositions by the aerosol route. This reference does not disclose pharmaceutical compositions wherein DCL has been specified as the active antihistamine.

The noted teaching of the Villani reference clearly motivates the ordinary practitioner to go out and find a decongestant to combine with DCL in a binary pharmaceutical composition. Similarly, the Berkow reference motivates one of ordinary skill to seek out an antihistamine to combine with pseudoephedrine to make effective compositions to treat allergic rhinitis and related conditions in humans. For these reasons the instant claims are deemed to lack patentable distinction in view of the noted prior art references which both provide motivation to produce the specific combination of active ingredients specified in claim **54** and generically in the remainder of the cited claims.

Therefore, the instant claimed binary pharmaceutical compositions comprising DCL and a decongestant, pseudoephedrine in particular, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments with respect to claims **48, 50, 52-54, 61 and 63-65** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **55-61 and 66-68** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Villani et al. '716** (PTO-1449 reference **AC**) in view of **Gennaro et al. (I)** (PTO-892 reference **S**).

The instant claims are directed to pharmaceutical compositions comprising DCL and an analgesic or non-steroidal anti-inflammatory drug (NSAID) selected from the group consisting of acetylsalicylic acid (asprin), acetaminophen, ibuprofen, ketoprofen and naproxen.

The Villani et al. reference at column 8, lines 42-46, the combination of DCL and "other therapeutic agents" in a single pharmaceutical composition of the kind found in claims ***5-8***,

particularly claim *5* which is directed to "an antihistaminic pharmaceutical composition comprising ... [DCL] ... ." This reference does not teach the specific combination of DCL and an analgesic or NSAID.

The Gennaro et al. reference discloses at p. 1131, column 2, numerous binary and ternary pharmaceutical compositions which contain antihistaminic activity and a mild analgesic or NSAID, "acetaminophen" in particular being specified in the fourth, seventh and eighth compositions listed. Looking elsewhere in the same reference, one finds beginning at p. 1109 an extensive listing of "Analgesics and Antipyretics" with the following compounds listed at the page in parentheses following each name:
i) acetylsalicylic acid (aka aspirin, p. 1110),
ii) acetaminophen (p. 1109),
iii) ibuprofen (p. 1116),
iv) ketoprofen (p. 1112) and
v) naproxen (p. 1118). At p. 1109, column 2, this references states concerning the complete listing of compounds which follows that "... Most of these agents affect both pain and fever. Consequently they are used widely for minor aches and pains, headaches and the general feeling of malaise that accompanies febrile illness, ..." This reference does not teach the specific combination of DCL and an analgesic or NSAID.

The teaching of the Villani et al. reference motivates the combination of the antihistamine DCL with other medicinal agents in binary pharmaceutical compositions of the kind specifically embodied at p. 1131 of the Gennaro et al. reference. The substitution of DCL for an antihistamine and the substitution of a different mildly analgesic substance or NSAID for acetaminophen are therefore deemed to have been variations well within the purview of the ordinary practitioner seeking to optimize the efficacy of the antihistaminic-analgesic binary composition when the antihistamine is DCL. And, while Villani does not specifically teach combinations of DCL with analgesics or NSAIDs, the Gennaro reference makes plain by its examples and other teachings that such combinations are notoriously well known and accepted variations in the pharmaceutical composition art, and are widely used to treat mild allergy-related nasal congestion.

Therefore, the instant claimed antihistaminic pharmaceutical compositions comprising DCL and an analgesic or NSAID selected from the group consisting of acetylsalicylic acid,

acetaminophen, ibuprofen, ketoprofen and naproxen would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments with respect to claims **55-61 and 66-68** have been considered but are deemed to be moot in view of the new grounds of rejection.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

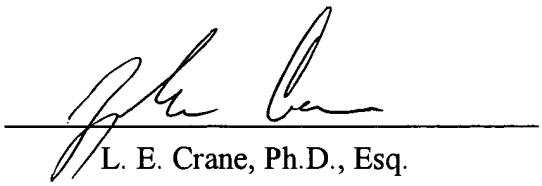
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
05/02/2005



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